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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,078	07/01/2003	John S. Patton	0005.16	6971

21968 7590 12/10/2004

NEKTAR THERAPEUTICS
150 INDUSTRIAL ROAD
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EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/613,078	PATTON ET AL.	
	Examiner	Art Unit	
	Gollamudi S Kishore, PhD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 26-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 26-35 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 11-12-04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 26-35 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim14-18 of U.S. Patent No. 6,685,967. Although the conflicting claims are not identical, they are not patentably distinct from each other because patented claims and instant claims recite the same insulin composition; patented claims recite in addition, "moisture content below 10 %. Since this expression includes even 0 %, meaning that the compositions contain no moisture at all, instant claims which recite no moisture limitations at all therefore, encompass the patented compositions.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 26-29 and 31-34 are rejected under 35 U.S.C. 102(a) or (e) as being anticipated by by Platz (5,354,562) of record.

Instant claims are drawn to a stable dry powder insulin composition produced by a method of spray drying a solution to produce substantially amorphous particles having an average size in the range from 0.1 to 5 micrometers.

Platz's disclosure relates to inhalation therapy involving the administration of a drug in aerosol from to the respiratory tract. According to Platz, "the present invention is useful for transforming polypeptide drugs into a powder form that is suitable for aerosol administration (col. 2, lines 13-15). Examples of such polypeptides include, inter alia, insulin (col. 2, line 21). The dry powder compositions further include pharmaceutical carriers such as lactose and trehalose (col. 2, line 51). Platz discloses a two step where the first step in the process for forming the polypeptides into micronized particles is lyophilization of buffer solution(col. 2, lines 38-40; col. 6, lines 4-5). Subsequently, the lyophilized polypeptide is size reduced in a grining mill, preferably a fluid energy mill also known as a jet mill

(col. 3, lines 3-5). The particle size of the milled powder disclosed by Platz appears to be essentially the same as the particle sizes recited in instant claims (Platz, col. 3, line 65 through col. 4, line 19). Thus, it would appear that Platz discloses a stable, dry powder insulin composition containing amorphous particles having a particle size essentially the same as the particle size recited in claim 26 (see also instant specification, page, 9, lines 20-31, in this regard). The burden is therefore, upon applicant to show that instant particles are patentably distinct from those disclosed by Platz.

This application is a continuation in part of 08/207,472 with the filing date of 3/7/04. The 102 (e) rejection will be reconsidered upon review of this application and determining the support.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 26-29 and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platz cited above.

The teachings of Platz have been discussed above. As pointed out above, instant particles appear to be either identical or slightly different from those disclosed by

Platz. Assuming that they are different since Platz is directed to the same inhalation therapy using particles of insulin, it is deemed obvious to manipulate the teachings of Platz, that is using spray drying instead of lyophilization to obtain the best possible particles.

7. Claims 30 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platz cited above, in combination with Chien (5,042,975) also of record.

The teachings of Platz have been discussed above. What is lacking in Platz is the teaching of the use of citrate as the buffer for insulin. Such a use however, would

have been obvious to one of ordinary skill in the art, with a reasonable expectation of success, since Chien teaches that citrate is a commonly used buffer in combination with insulin (example 3 on col. 17).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM-4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK